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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/053,625	11/02/2001	Gerardo Castillo	PROTEO.P18	5292

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EXAMINER

TATE, CHRISTOPHER ROBIN

ART UNIT

PAPER NUMBER

1654

DATE MAILED: 03/11/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.  
10/053,625

Applicant(s)  
Castillo et al.

Examiner  
Christopher Tate

Art Unit  
1654

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on Feb 6, 2003
- 2a) ☒ This action is FINAL. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1, 8, 10-13, 18, 22, 31, and 33-38 is/are pending in the application.
- 4a) Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claims 1, 8, 10-13, 18, 22, 31, and 33-38 are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some\* c) ☐ None of:

- ☐ Certified copies of the priority documents have been received.
- ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
- ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\*See the attached detailed Office action for a list of the certified copies not received.

- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

a) ☐ The translation of the foreign language provisional application has been received.

- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- ☐ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). \_\_\_\_\_
- ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other:

Art Unit: 1654

### **DETAILED ACTION**

Upon further review and consideration, an additional Restriction and Election of Species requirement is deemed necessary, as set forth below.

#### ***Election/Restriction***

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- VIII. Claims 1, 8, 31 and 33-38, drawn to a pharmaceutical agent comprising a dried plant material and a method of making the dried plant material, classified in class 424, subclass 725+.
- IX. Claims 10-13, 22, 31 and 33-38, drawn to a pharmaceutical agent comprising one or more isolated plant material fractions associated with HPLC graphic display peaks which are obtained via the steps recited in claims 10-13 and/or 22, and a first method of preparing the one or more isolated plant material fractions, classified in class 514, subclass 100+, for example.
- X. Claims 18, 31, and 33-38, drawn to a pharmaceutical agent comprising one or more isolated plant material fractions associated with HPLC graphic display peaks, which are obtained via the steps recited in claim 18, and a second method of preparing the one or more isolated plant material fractions classified in class 514, subclass 100+, for example.

The inventions are distinct, each from the other because of the following reasons:

Art Unit: 1654

The product of Group VIII requires an singular dried plant material as the pharmaceutical agent (e.g., prepared by the process steps recited in claims 1 and 8 - which does not require HPLC fractionation), whereas the products of Groups IX-X require one or more isolated plant material fractions obtained by HPLC fractionation.

The pharmaceutical agent of Group IX does not necessarily require any or all of the plant material fraction(s) of the Group X product. Conversely, the pharmaceutical agent of Group X does not necessarily require any or all of the plant material fraction(s) of the Group IX product. In addition, the extraction process of Group VIII does not require HPLC fractionation, whereas the extraction processes of Groups IX and X do. Further, the extraction process employed by Group IX in obtaining such plant material fractions require various steps which are distinct from those of the extraction process of Group X.

In addition, with respect to Groups IX and X, this application contains claims directed to the following patentably distinct species of the claimed invention: The one or more distinct isolated plant material fractions instantly claimed - e.g., as recited in claims 11-13, 18, and 22.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species (elect one of the recited plant material fractions, or elect a group of plant material fractions, which identify what the elected pharmaceutical agent material actually comprises) for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable.

Currently, claim 31 is generic.

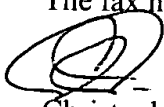
Art Unit: 1654

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christopher R. Tate whose telephone number is (703) 305-7114. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda Brumback, can be reached at (703) 306-3220. The Group receptionist may be reached at (703) 308-0196. The fax number for art unit 1654 is (703) 872-9306.

  
Christopher R. Tate  
Primary Examiner, Group 1654